PATENT

DOCKET NO.: JANS-0027/JAB1498 US

Application No.: 10/030,202

Office Action Dated: October 20, 2004

REMARKS/ARGUMENTS

Claims 1 to 4, 6, 8 to 10, 13 to 15, and 18 to 21 are pending in this application. In response to the appeal brief filed on August 2, 2004, the prosecution of this application has been reopened. The claims are rejected as follows:

■ claim 1 is newly rejected under 35 U.S.C. § 102(b) over US-A-5,360,807;

claim 1 is newly rejected under 35 U.S.C. § 102(b) over US-A-4,695,569;

■ claims 1 to 4, 10, 13, 15, and 18 to 21 stand rejected under 35 U.S.C. § 103(a) over US-A-5,360,807; and

■ claims 1 to 4, 10 to 13, 15, and 18 to 21 stand rejected under 35 U.S.C. § 103(a) over US-A-4,695,569.

Claims 6, 8, 9, and 14 are not specifically addressed in the latest Office Action. Based on a telephonic interview with Examiner Habte on November 8, 2004, applicants believe that claim 6 is objected to because it depends from rejected base claims but would be otherwise allowable if rewritten in independent form. Claims 8, 9, and 14 are believed to be rejected. Applicants are herein canceling claims 2 and 11 to 22, without prejudice or disclaimer, and amending claims 1, 3, 4, 6, 8, 9, and 10. Upon entry of this amendment, claims 1, 3, 4, 6, 8 to 10 will be pending.

Amendments to Claims

Applicants are herein amending claim 1 to present it as a method of treatment claim rather than a method of manufacturing a medicament for the treatment of respiratory syncytial viral infections, as suggested by the Examiner. Applicants are herein amending claim 10 to incorporate the subject matter of cancelled claim 2 and amending claims 3, 4, 6, 8, and 9 to have them properly depend from claim 10. Applicants are also amending claims 8 and 9 to correct claim form issues (addition of "or"). Applicants submit that the amendments to the claims do not introduce new matter and are fully supported by the specification and claims, as originally filed, including claim 10 and cancelled claim 2.

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Applicants are herein canceling claims 2 and 11 to 22, without prejudice or disclaimer. Applicants reserve the right to file one or more continuing applications to the cancelled subject matter.

Rejections under 35 U.S.C. § 102(b)

Claim 1 is newly rejected under 35 U.S.C. § 102(b) as allegedly anticipated by US-A-5,360,807 and by US-A-4,695,569. Applicants are herein amending claim 1 to present it as a method for treating respiratory syncytial viral infections. Applicants submit that neither of

the cited references discloses, teaches, or suggests any method for treating respiratory

syncytial viral infections. Accordingly, applicants request withdrawal of both rejections of

claim 1, as amended, under 35 U.S.C. § 102(b).

Rejection under 35 U.S.C. § 103(a) with respect to US-A-5,360,807

Claims 1 to 4, 10, 13, 15, and 18 to 21 stand rejected under 35 U.S.C. § 103(a) over

US-A-5,360,807. Applicants respectfully traverse the rejection.

Applicants submit that there is no motivation to modify the cited reference to achieve applicants' claimed invention, as US-A-5,360,807 is directed to antiallergic and antihistamine

compounds whereas applicants' claimed methods of treatment employing novel and known

compounds for the treatment of respiratory syncytial viral infections.

Applicants submit that it has not been established in the Office Action that the claimed

invention is prima facie obvious. To establish a proper prima facie rejection, the following

elements must be shown:

(1) the reference(s) is (are) available as prior art against the claimed invention;

(2) the motivation (explicit or implicit) provided by the reference(s) that would have

rendered the claimed invention obvious to one of ordinary skill in the art at the time of

the invention;

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(3) a reasonable expectation of success;

- (4) the basis for concluding that the claimed invention would have been obvious to do, not merely obvious to try; and
- (5) the reference(s) teach(es) the claimed invention as a whole.

Applicants submit that elements 2, 3, 4 and 5 have not been established. Hence, a *prima facie* obviousness rejection is improper. *In re Grabiak*, 769 F.2d 729, 733, 226 U.S.P.Q. 870, 873 (Fed. Cir. 1983).

In the Office Action, it is alleged that some of the compounds of the invention are structural homologues of the compounds disclosed in US-A-5,360,807. It is further alleged that a skilled artisan would be motivated to modify the reference to achieve the presently claimed invention because such compounds "would be expected to possess similar utilities." Applicants disagree that the cited reference and the claimed invention "possess similar utilities." US-A-5,360,807 discloses the use of its compounds in methods of treating warm-blooded animals suffering from allergic diseases, whereas the claimed invention is directed to compounds useful in methods for treating respiratory syncytial viral infections. Applicants submit that allergic diseases and respiratory syncytial viral infections are different:

An *allergy* is a state of hypersensitivity induced by exposure to a particular antigen (allergen) resulting in harmful immunologic reactions on subsequent exposures, the term is usually used to refer to hypersensitivity to an environmental antigen (atopic allergy or contact dermatitis) or to drug allergy. On-line Medical Dictionary, Academic Medical Publishing & CancerWEB (previously submitted)

A respiratory syncytial viral infection is an infection (an invasion and multiplication of microorganisms in body tissues) caused by the RNA virus (a member of the Paramyxoviridae family). The virus is a major pathogen in the upper and lower respiratory tract in both infants and younger children. Respiratory syncytial virus manifestations include bronchiolitis, pneumonia and croup.

On-line Medical Dictionary, Academic Medical Publishing & CancerWEB (previously submitted)

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Furthermore, the Office Action does not establish a connection between the treatment of allergic diseases and the treatment of respiratory syncytial viral infections, a burden that must be carried by the Office not the applicant to establish *prima facie* obviousness, as incorrectly stated in the Office Action. It is respectfully submitted that a skilled artisan would have no expectation that the compounds of US-A-5,360,807 would be useful in methods of treating respiratory syncytial viral infections and thus would have no motivation to modify the reference, especially in a manner to achieve applicants' claimed method and compounds.

Solely for the purpose of expediting prosecution, applicants are herein canceling claims 2, 13, 15, and 18 to 21, without prejudice or disclaimer, rendering moot the obviousness rejection with respect to these claims. In light of the amendments and arguments presented herein, applicants respectfully request withdrawal of the rejection of canceled claims 2, 13, 15, and 18 to 21 and of pending claims 1, 3, 4, and 10, as amended, under 35 U.S.C. § 103(a) in view of US-A-5,360,807.

Rejection under 35 U.S.C. § 103(a) with respect to US-A-4,695,569

Claims 1 to 4, 10 to 13, 15, and 18 to 21 stand rejected under 35 U.S.C. § 103(a) over US-A-4,695,569. Applicants respectfully traverse the rejection.

Applicants submit there is no motivation to modify the cited reference to achieve applicants' claimed invention. The compounds cited by the Office from US-A-4,695,569 are different than the compounds of the claimed invention. Furthermore, these prior art compounds are *intermediates* in the preparation of compounds for treating allergic diseases (see Abstract, for example), *i.e.*, a method of treatment different than claimed in the present application.

The Office has also failed to show why one skilled in the art would employ the compounds disclosed in US-A-4,695,569 compounds to treat viral infections. US-A-4,695,569 is directed to antiallergic and antihistamine compounds whereas applicants' Page 15 of 16

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claimed invention is directed to novel compounds and methods of treatment employing novel and known compounds for the treatment of respiratory syncytial viral infections. Applicants, therefore, submit that it has not been established in the Office Action that the claimed invention is *prima facie* obvious.

Solely for the purpose of expediting prosecution, applicants are herein canceling claims 2, 11 to 13, 15, and 18 to 21, without prejudice or disclaimer, rendering moot the obviousness rejection with respect to these claims. In light of the amendments and arguments presented above, applicants respectfully request withdrawal of the rejection of canceled claims 2, 11 to 13, 15, and 18 to 21 and of pending claims 1, 3, 4, and 10, as amended, under 35 U.S.C. § 103(a) over US-A-4,695,569.

Conclusions

Applicants respectfully request:

- (1) entry of the amendments to the claims;
- (2) reconsideration and withdrawal of the rejections of the claims based on the foregoing remarks and arguments; and
- (3) allowance of claims 1, 3, 4, 6, 8 to 10.

If the Examiner is of a contrary view, the Examiner is requested to contact the undersigned attorney at (215) 557-3861.

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